



December 8, 1999

Jane E. Henney, MD
Commissioner, Food & Drug Administration
Parklawn Building, Room 1471, 5600 Fishers Lane
Rockville, MD 20877

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Re: Docket number 99P-2077/CP 1,
Citizen Petition for a Regulation or Guideline to Label Medical Devices Containing
Phthalate Plasticizers and to Establish a Program to Promote Alternatives

Dear Dr. Henney:

I am writing on behalf of the Natural Resources Defense Council, a national, non-profit, environmental and public interest organization with over 450,000 members nation-wide, to state that I support Health Care Without Harm's Citizen's Petition, docket number 99P-2077/CP 1, in its entirety.

I urge the Food and Drug Administration to require all polyvinyl chloride (PVC) medical devices that may leach plasticizers to include a clearly worded warning label, and to establish a program that encourages the development and use of plasticizer-free alternatives to PVC medical devices.

Cancer patients receiving Taxol or Taxotere are already protected by labeling that warns against the administration of those drugs using PVC, because those two drugs accelerate the leaching of plasticizers. But other patients who risk high levels of exposure to these chemicals are not being warned. Dialysis patients, premature infants and people who receive long-term intravenous or tube feeding therapies are all at risk of Taxol-like exposures to plasticizers without the protection of Taxol-like warnings.

Please keep me informed of the status of your actions. Thank you for your time.

Sincerely,

Gina M. Solomon, M.D., M.P.H.
Senior Scientist

99P-2077

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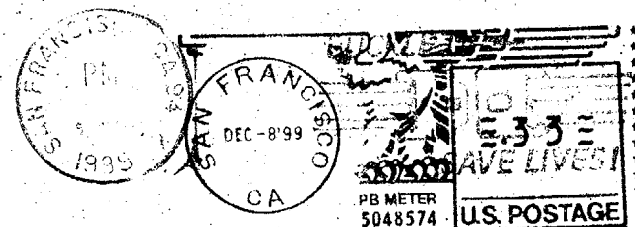
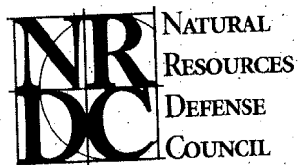
71 Stevenson Street
Suite 1825
San Francisco, CA 94105
415 777-0220
Fax 415 495-5996

www.nrdc.org

6310 San Vicente Boulevard
Suite 250
Los Angeles, CA 90048
323 934-6900
Fax 323 934-1210

1200 New York Ave., N.W.
Suite 400
Washington, DC 20005
202 289-6868
Fax 202 289-1060

40 West 20th Street
New York, NY 10011
212 727-2700
Fax 212 727-1773



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71 Stevenson Street
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20432+1750

